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TECH CENTER 1600/2900  
#5 10/16/01

653.1006

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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SEP 19 2001  
TECH CENTER 1600/2900

Re: Application of: Donald P. REITBERG  
Serial No.: 09/872,815  
Filed: June 1, 2001  
For: **Single-Patient Drug Trials Used With  
Accumulated Database: Flowchart**

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

September 10, 2001

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97 (b), before the mailing date of a first Office Action on the merits.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

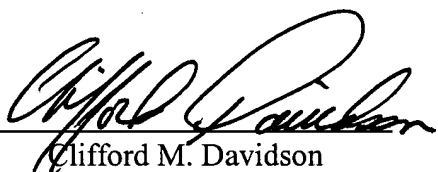
The Examiner's attention is respectfully directed to references AO, AP, AQ, AR and BM, which were discussed (or cited by the Examiner) during the prosecution of a related case, U.S. Serial No. 08/331913 (now U.S. Patent No. 6,242,463).

Applicants respectfully advise the Examiner of the following related U.S. patent and applications which are commonly assignable to the owners of the instant application: U.S. Serial No. 08/331,913, "Method And Kit For Treating Illnesses," filed October 31, 1994, (now U.S. Patent No. 6,242,463); U.S. Serial No. 09/823,329, "Method And Kit For Treating Illnesses," filed March 30, 2001; U.S. Serial No. 09/872,430, "Single-Patient Drug Trials Used With Accumulated Database: Genomic Markers," filed June 1, 2001; and U.S. Serial No. 09/872,506, "Single-Patient Drug Trials Used With Accumulated Database: Risk of Habituation," filed June 1, 2001.

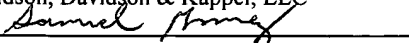
It is believed that no fee is due for this submission. If a fee is deemed to be due, the Commissioner is hereby authorized to deduct the fee from Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By   
Clifford M. Davidson  
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I hereby certify that the documents referred to as attached therein and/or fee are being deposited with the United States Postal Service with sufficient postage as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20213" on September 10, 2001.  
Davidson, Davidson & Kappel, LLC  
By: 

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
653.1006SERIAL NO.:  
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## LIST OF PRIOR ART CITED BY APPLICANT

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA						

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
AB 0 4 5 9 3 8 7	04/12/91	Europe	G01N	33/533	English

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AC	Sheather-Reid, R. et al., "Efficacy of Analgesics in Chronic Pain: A Series of N-of-1 Studies", <u>Journal of Pain and Symptom Management</u> , Vol. 15, No.4, 1988; pgs. 244-252.
AD	Jaeschke, R. et al., "Clinical Usefulness of Amitriptyline in Fibromyalgia: Results of 23 N-of-1 Randomized Controlled Trials, <u>The Journal of Rheumatology</u> , Vol. 18, No. 3, 1991; pgs. 447-451.
AE	Patel, A. et al., "Clinical Usefulness of n-of-1 Randomized Controlled Trials in Patients with Nonreversible Chronic Airflow Limitation", <u>AM REV RESPIR DIS</u> , 1991; 144:962-964.
AF	Balestra, D. et al., "Ulcerative Colitis and Steroid-Responsive, Diffuse Interstitial Lung Disease", <u>JAMA</u> , July 1, 1988; Vol. 260 No. 1
AG	Max, M.B. et al., "The Design of Analgesic Clinical Trials", <u>Advances in Pain Research and Therapy</u> , Vol. 18, 1991; 178-192.
AH	Cook, D. et al., "A Diagnostic and Therapeutic N-of-1 Randomized Trial", <u>Canadian Journal of Psychiatry</u> , Vol. 38, 1993; 251-254.
AI	Guyatt, G.H. et al., "A clinician's guide for conducting randomized trials in individual patients", <u>CMAJ</u> , Vol. 139, 1988; 497-503.
AJ	Wulff, H.R., "Single Case Studies An Introduction", <u>Scandinavian Journ. of Gastroenterology</u> , 1988, Vol 23. S. 147, pgs. 7-10.
AK	Keller, J. et al., "An N of 1 Service: Applying the Scientific Method in Clinical Practice", <u>Scandinavian Journ. of Gastroenterology</u> , 1988, Vol 23. S. 147, pgs.22-29.
AL	Guyatt, G.H. et al., "N-of-1 Randomized Trials for Investigating New Drugs", <u>Controlled Clinical Trials</u> , 11:88-100 (1990).
AM	Larson, E.B., "N-of-1 Clinical Trials A Technique for Improving Medical Therapeutics", <u>The WESTERN JOURNAL OF MEDICINE</u> , 1990; 52-56.
AN	Biosis 94:537363 (1994)
AO	Guyatt <i>et al.</i> (1990) N-of-1 Randomized Trials-Where Do We Stand? <u>Western Journ. of Med.</u> , 152(1): 67-8.
AP	Johannsen <i>et al.</i> (1991) Combined Single Subject Trials. <u>Scandinavian Journ. of Primary Health Care</u> , 9(1): 23-7.
AQ	Johannsen <i>et al.</i> (1992) Cimetidine On Demand In Dyspepsia. <u>Scandinavian Journ. of Gastroenterology</u> , 27(3): 189-95
AR	Spilker, Bert, "Planning Special Types of Clinical Trials: Single-Patient Clinical Trials" <u>Guide to Clinical Trials</u> , Part III, Chapter 38 pgs277-282.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
653.1003SERIAL NO.:  
09/872,430**RECEIVED**

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): REITBERG, Donald P.

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DOCUMENT NUMBER

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## FOREIGN PATENT DOCUMENTS

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COUNTRY

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SUBCLASS

TRANSLATION

BB

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BC

Langer, C. et al., "The Single Subject Randomized Trial A Useful Clinical Tool for Assessing Therapeutic Efficacy in Pediatric Practice", Clinical Pediatrics, Nov. 1993; 654-657.

BD

Guyatt, G.H., et al., "The n-of-1 Randomized Controlled Trial: Clinical Usefulness", Annals of Internal Medicine, 1990; 112:293-299.

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Spiegelhalter, D., "Statistical Issues in Studies of Individual Response", Scandinavian Journ. of Gastroenterology, 1988, Vol 23. S. 147, 40-45.

BF

Larson, E.B. et al., "Randomized Clinical Trials in Single Patients During a 2-Year Period", JAMA, Vol. 270, No. 22, 1993; 2708-2712.

BG

Robin, E. et al., "Single Patient Randomized Clinical Trial Opiates for Intractable Dyspnea", CHEST, 1988; 90:888-892.

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Gibaldi, M., et al., "Single-Patient Drug Trials", Perspectives in Clinical Pharmacology, Vol. 4, No. 11, 1986, pages 81-83

BI

Guyatt, G., et al., "Determining Optimal Therapy-Randomized Trials in Individual Patients", The New England Journal of Medicine, Vol. 14, No. 14, 1986, pages 889 - 892

BJ

McLeod, R.S., et al., "Single-Patient Randomised Clinical Trial", The Lancet, 1986, pages 726-728

BK

Larson, E.B., et al., "Randomized Clinical Trials in Single Patients During a 2-Year Period", JAMA, Vol. 270, No. 22, pages 2708-2710

BL

Anonymous, May 31, 1986, "Single-Patient Trials" Editorial Section, The Lancet

BM

Zucker, D.R., et al., "Combining Single Patient (N-of-1) Trials to Estimate Population Treatment Effects and to Evaluate Individual Patient Responses to Treatment", Journal of Clinical Epidemiology, Vol. 50, No. 4, 1997; pp. 401-10.

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